

Atty. Docket No: EFFR0010U-US
Serial No: 10/10/092,083

Remarks

Claim 48 has been cancelled and added to the main claim. Claims 44 – 47 and 49 – 52 are active in the case. The present invention relates to a an improved method for treating osteoporosis with an effervescent bisphosphonate solution having very high buffering capacity.

The Rejection of Claims under 35 U.S.C. § 103

The rejection of Claims 44 – 52 under 35 U.S.C. § 103 as being unpatentable over Katdare et al. (US 5,853,759) is respectfully traversed. The reference teaches generically that bisphosphonates can be administered in effervescent solutions, but it does not recognize the desirability of using a large amount of effervescing components to produce high buffering capacity and rapid ejection of the solution from the stomach, thus preventing gastric irritation. (Hayward Dec. para. 7). Examiner has pointed to disclosure in Katdare et al. where the components add up to 3.365g. As amended, the invention is directed to compositions having a much larger amount of the buffering system, with total weights of about 5 to 6 grams, and they have a relatively large percentage of acid. The smaller quantities of effervescing system in the Katdare et al. formulations would not promote rapid ejection of the bubbling solution from the stomach, and so are prone to cause irritation (Hayward Decl. para. 11). Consequently, this ground of rejection is unsustainable, and should be withdrawn.

The rejection of Claims 44 – 52 under 35 U.S.C. § 103 as being unpatentable over Daifotis et al. (US 5,994,329) is respectfully traversed.

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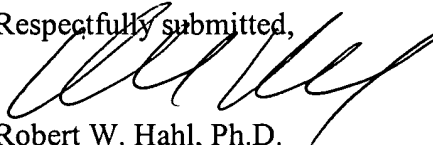
Example 8 of Daifotis et al. is a liquid composition but it not effervescent and so is not at all similar to applicants' invention. The Examiner points to generic language at col. 12, line 3, of the reference which states that oral administration can be done with "tablets, capsules, elixirs, syrups, effervescent compositions, powders, and the like, and consistent with conventional pharmaceutical practices." However, this disclosure silent with respect to the nature of the effervescent compositions and is much farther from the present invention than Katdare et al., discussed above. Accordingly, the claims are patentable over Daifotis et al. for at least the same reasons as Katdare et al.

Conclusions

Applicants submit that the case is now in condition for allowance. Early notice to that effect is earnestly requested.

If it is deemed helpful or beneficial to the efficient prosecution of the present application, the Examiner is invited to contact Applicant's undersigned representative by telephone.

Respectfully submitted,



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